AUG 1 2001

K012217

510(K) SUMMARY

M5T Instant Fever Thermometer

Applicant's Name:

Medisim Ltd.
The Technology Park Manhat
Jerusalem 96251, Israel
Tel: 972-2-679-9204
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Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
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Date Prepared:

July, 2001

Trade Name:

M5T Instant Fever Thermometer

Classification Name:

Thermometer, Electronic, Clinical

Classification:

Class II; Product Code 80FLL; Regulation No. 880.2910.

Statement of Substantial Equivalence:

The M5T is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available Up-Grade and Up-Grade Pro Thermometer. The changes between the two thermometers include removal of the heater; the pre-heating control and overheating protection, prolonged measuring time, and subsequently slight change in the thermometer design.

Device Description:

The M5T is a compact predictive clinical thermometer designed to measure human body temperature by detecting heat from three different body sites: axilla, rectum and mouth, by using the heat conduction principle and prediction.

The M5T is designed to calculate the maximum temperature of a probe in contact with the body site. The temperature reading range is from 35.0°C to 42.0°C (95.5°F to 107.6°F) and the time of measurement varies between 8 to 10 seconds.

The LCD, push button, battery, microprocessor and the PCB are located in one housing, which includes upper cover, lower cover and the battery cover. The entire device is compact, lightweight, small in size, easy to use and portable.

Indications:

The M5T is non-sterile, reusable clinical thermometer intended for the determination of oral, rectal and axillary body temperature determination in humans.

Performance Data:

A clinical study was performed in order to evaluate the safety and performance of the M5T following the heater removal. The study results demonstrated that the M5T is safe and effective without raising new safety and/or effectiveness issues

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Medisim Limited
C/O Ms. Dorin Teich
Quality Assurance Manager
Push-med Limited
117 Ahuzah Street
Ra'ananna,
ISREAL

Re: K012217
Trade/Device Name: M5T Instant Fever Thermometer
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: July 10, 201
Received: July 16, 2001

Dear Ms. Teich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K012217

Device Name: M5T Instant Fever Thermometer

Indications for Use:

The M5T is non-sterile, reusable clinical thermometer intended for the determination of oral, rectal and axillary body temperature determination in humans.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Rebecca Cicenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012217